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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/652,797

Applicant(s)

JOHNSON, DAVID A.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 49-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 49-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/22/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of The Claims

Claims 7-47 have been canceled. Claims 1-6 have been amended. New claims 49-55 have been added. Currently, claims 1-6 and 49-55 are under Examination. The said claims are drawn to a process for the preparation of the compounds described in claim 1, wherein the variable groups are defined as:

- R is hydrogen or aldehyde
- R₁ is hydrogen and
- R₂ is selected from hydrogen, substituted or unsubstituted C₁₋₂₀ alkyl groups.

Thus the current Examination is directed to a process for the preparation of the compounds as described above, see claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 49-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicants claim a process for the preparation of a series of compounds as described in claim 1. However, there is a clear lack of enablement in the said process that a patent given to the said claims would obscure a whole research area without any benefit to the public because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant Lack of enablement rejection is based on the following factors, see *In re Wands*, 8 USPQ2d 1510, and MPEP 2164.

The Breadth of the Invention

Applicants claim process wherein a series of compounds as defined in claim 1 are prepared. On the specification it is described that once the said derivatives are prepared, they are used as intermediate in a more complex synthesis in the preparation of vaccine used as antigen, see specification, pages 4-5. Thus, the preparation of the said derivatives is the angular stone in more complex synthesis that would allow the preparation of the said vaccines. Applicants claim that the said derivatives are prepared by:

- Monobenylation of hydroquinone and
- Conducting an ortho-formylation of the product of step (a).

However, there is:

- No identification of the reactant(s) used and/or the reaction-conditions required in the monobenylation of hydroquinone
- No identification of the compound(s) obtained as product of the monobenylation of hydroquinone

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- The reactant(s) and conditions required in the stereo controlled formylation of the non-identified substrate or intermediate.

2) The Nature of the Invention

The nature of the invention, in a general sense is a process for the preparation of organic compounds that would further be used in the preparation of other more complex compounds and/or in pharmaceutical compositions. Essential for the success of the said final utility is the preparation of the compounds described in claim 1. Applicants claim that the said compounds are novel.

3) The existence of working examples

Applicants provide no example of the preparation of the said compounds wherein the claimed process is disclosed or suggested. Example 1 on page 51 of the instant specification described a method to prepare a methyl ester embraced by the said compounds described in claim 1, however, the said method is totally different from the one being described in the instant claims. On page 10 of the Preliminary Amendment, Applicants argues that:

- “Such a process is described in the specification at pp. 21-25. Methyl esters are disclosed in the examples. While in those examples they are produced by a different process they clearly are contemplated as being a part of the inventive concept and as compounds that **could be** produced by the now-claimed process”.

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The Examiner would like to point out that Applicant's instant claims are not drawn to compounds if not to a process of preparation of synthetic organic compounds.

Moreover, the written description requirement does not substitute the enablement requirement. What kind of process is the one being claimed that not even the same Applicants used it in the preparation of the said compounds?

4) State of the Prior art

No prior art teaching or suggesting a preparation method for the compounds described in the instant claims was found. The closest art relevant to Applicant process was found in Boulos et al, J. Chem. Soc. Perkin Trans, 1997, pp2925-2929, wherein a synthesis for a isomeric form of those embraced in formula 1 was prepared by a non-related process to the one described in the instant claims.

Therefore, as state in ***Genentech Inc. vs. Novo Nordisk A/S***, (CA FC) 42 USPQ2d 1001, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "Patent protection is granted in return for an enabling disclosure of an invention, not for a vague intimations of general ideas that may or may not be workable". Thus, a person skilled in the art would need to carry out undue experimentation in order to practice the claimed invention because of the above factors and because the proper reaction conditions and reactants required in the monobenylation of hydroquinone would need to be found and the obtained product would need to be purify and elucidated and further subjected to different formylation reactions conditions until the proper reactants and ortho-formylation conditions are

found in order to prepare different substrates embraced by the claimed method, so they can be further used in more complex synthesis and/or in pharmaceutical compositions. Reaction conditions such as reaction temperatures, polarity of substrates, solvent or solvent combinations, chromatographic techniques, are examples of the extensive conditions to be determined via undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and ambiguous because the variable R2 is defined as a substituted C1-20 alkyl group, among other alternatives. Nonetheless, it is unclear what organic moieties are embraced by the term substituted. What are the organic groups embraced by the said terms?

Claim 1 is indefinite and indeterminate because in the said claim a process for the preparation of derivatives having the described formula presented in claim 1 is claimed.

Applicants claim that the said compounds are prepared by:

- The monobenylation of hydroquinone and the further

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- Ortho-formylation of the product of the first step (a).

However, there is no identification of the product obtained in the said first step (a) as an intermediate nor the required steps required to carry out the claimed ortho-formylation of the non-specified intermediate. What is the product obtained after benzylation of hydroquinone? How the ortho-formylation of the said intermediate is achieved?

Claims 2-6 recites the limitation "The process of claim 1, wherein...." Followed by a series of variable definitions:

In claim 2, R1 is defined as a mono- or disaccharide

In claim 3, R1 is defined as a glucuronic group

In claims 5 and 6, R1 is defined as a glucuronic group.

There is insufficient antecedent basis for this limitation in the claim, since in claim 1 the variables are defined as:

- R is hydrogen or aldehyde
- R1 is hydrogen and
- R2 is selected from hydrogen, substituted or unsubstituted C₁₋₂₀ alkyl groups.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hector M. Reyes, whose telephone number is (571) 272-0691. The Examiner can normally be reached Monday through Friday from 9:30 to 5:30pm.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Ms. Rita Desai can be reached at (571) 272-0684.

Hector M. Reyes, PhD JD

Reg # P-54,846

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July 27, 2004

Rita Desai
7/28/04